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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/330,262 06/11/99 THEVELEIN J 6-1032-041

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EXAMINER

YUCCEL, I

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

06/20/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/330,262	THEVELEIN ET AL.
	Examiner Yucel Remy	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 December 2000.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-25 and 36-41 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 18) Interview Summary (PTO-413) Paper No(s). _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: *detailed action*.

DETAILED ACTION

Claims 1-41 are pending in the application. This Office action is in response to the election filed 18 December 2000.

Election/Restrictions

Applicant's election of group I (claims 1-25 and 36-41) in Paper No. 5, filed 18 December 2000 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 26-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Specification

Applicants make numerous references to deposited strains of yeast throughout the specification (at least at page 13, lines 1-13 and page 58, lines 10-15 and claims 19-23). While it appears that a deposit has been made, it has not been perfected because the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description. The present specification does not provide all of the above information (for example dates of deposit or taxonomic descriptions).

Applicants are encouraged to review the entire specification and provide the above data as appropriate, as well as fill in the blanks found in claims 19-23.

Additionally, Applicants must provide the following statement/declaration to perfect their deposit:

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection

Art Unit: 1636

or rejection based on a lack of availability of biological material. See 37 CFR 1.801 through 1.809. Such a declaration:

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent.
5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. 1.14 and 35 U.S.C. § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

It is noted that the specification states that the deposits were made in accordance with the Budapest Treaty; however the statement that all restrictions on the availability to the public of

the material so deposited will be irrevocably removed upon the granting of a patent is not present in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-25 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is objected to under 35 U.S.C. §112, first paragraph, as failing to provide an enabling disclosure for the claimed invention.

It is apparent that certain, particular strains (I-2031 through I-2036, AT251, AT252, and AT254) are required to practice the claimed invention. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. These strains appear to be the result of random mutagenesis induced by chemical or UV treatment. Because of the random nature of the mutagenesis, it is not predictable, nor probable that the skilled artisan would ever be able to reproduce exactly the mutation or mutations in the deposited strains or even recognize that he has done so. While the skilled artisan would be able to screen for a certain phenotype, because the specification does not set forth all of the mutations (both those which contribute to the phenotype as well as silent

Art Unit: 1636

mutations), the skilled artisan would never know if he arrived at the claimed strains. As discussed above, the deposit of these strains has not been perfected yet and thus, the claims are not enabled.

This is precisely why broader claims 24 and 25 are also rejected. Even if the deposit were perfected, outside of a general phenotype (*fil*) which appears to result through many routes (i.e. mutations in more than one pathway can result in the *fil* phenotype), the specification fails to set forth the salient features of the strains recited in these strains.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 and 36-41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At the outset it is noted that the claims are not drafted according to the conventions of U.S. practice. The Examiner has attempted to list every issue for each of the claims to present as complete an action as possible in the interest of compact prosecution. However, due to the large number of claims and problems, some instances may have been inadvertently overlooked.

Applicants are urged to review each claim carefully and make the necessary corrections as appropriate.

Regarding claim 1 and its dependent claims, the phrase "such as" in line 3 renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP §2173.05(d).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1-14 recite several broad recitations followed by narrower statements of the range/limitation. The claims start by reciting "eukaryotic strains" (of what, it is not clear) which is narrowed to "*Saccharomyces cerevisiae*." Applicants should amend the claims to recite strains of *Saccharomyces cerevisiae* to obviate this rejection and avoid enablement issues raised by broad terms such as "eukaryotic strains." This "broad/narrow" problem exists throughout the claims, occurring at lines 19, 21-24, and 26-28 of claim 1 alone, lines 3-4 of claim 5, lines 2-3 of claims 10 and 11, lines 6-7 of claims 12 and 13, and line 3 of claim 14.

The recitation "classic mutagenic treatment" in line 5 of claim 1 renders the claims indefinite because there is no one set of mutagenesis treatments which are regarded as "classic." In the art of yeast genetics as of 1999, several recombinant mutagenic treatments would also be considered "classic." Applicants raise concerns about genetically modified organisms (GMOs).

Without commenting on the merits of these concerns, (especially when one still introduces mutations into the genes of yeast as a result of exposure to chemicals or UV). Perhaps a better approach would be to use language (which enjoys support of the specification) which conveys the idea that the mutagenesis is not recombinant in nature, rather than using the recitation "classic."

Lines 10-11 of claim 1 are problematic because it is not clear what is meant by "active metabolic state of this sugar."

At line 16 of claim 1, the recitation "i.e." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

In claim 2, it not clear what is meant or encompassed by the terms "useful secondary property" and "hampering property" ("useful" for what" and "hampering" what?).

The recitation "mutagenesis treatment" found in lines 1 of claim 6 lacks antecedent basis in the claims.

The recitation "new" found in claims 1 (see line 10) and 7-25 is not appropriate because, by definition, all inventions are "new" or "novel." In addition, all of the claims should start with either "A" or "The," for example "A process" or "A yeast strain." One should always claim in the singular form, therefore, Applicants should carefully review all the claims to identify instances such as in claim 12, drawn to "new industrial yeast."

In claim 10 and 11, it is not clear if the claims must be limited to glucose (another example of the broad/narrow problem discussed above).

Regarding claims 24 and 25, the phrase "same kind than" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "same kind than"), thereby rendering the scope of the claim(s) unascertainable. See MPEP §2173.05(d).

In claim 14, line 5, it is not clear what are the metes and bounds of the claim because of the undefined recitation "same characteristics."

Claims 36-41 provide for the use of yeast strains but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 36-41 are rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp.131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6 (d)). The Group 1600 FAX numbers are (703) 308-4242 or (703) 305-3014. Unofficial faxes may be sent to the examiner at (703) 305-7939. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative.

Art Unit: 1636

NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of
duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Remy Yucel, Ph. D. whose telephone number is (703) 305-1998. The examiner can normally be reached on Monday through Fridays from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to patent analyst Dianiece Jacobs whose telephone number is (703) 305-3388.

Remy Yucel

Remy Yucel, Ph. D.
Primary Patent Examiner
Technology Center 1600
18 June 2001